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P0570 Precision of the FilmArray® pneumonia panel - considerations for interpreting relative abundance of bacterial nucleic acids in lower repiratory specimens

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Background: FilmArray Pneumonia Panel rapidly identifies viruses, bacteria and antimicrobial resistance genes in bronchoalveolar lavage and sputum specimens. Laboratory methods providing information about bacterial abundance are critical for lower respiratory specimen diagnostic evaluation. Therefore, 'semi-quantitative' estimates of nucleic acid abundance are provided for 15 bacteria. Estimated abundance is reported in bins over a clinical range (Not Detected, 10^4, 10^5, 10^6, and ≥10^7 copies/mL), with each bin encompassing the indicated value (e.g. 10^5 copies/mL) ± 0.5-log. Bin results provide absolute and relative estimates in complex specimens, however, use of bins with discrete boundaries has consequences for precision that must be considered when interpreting results.

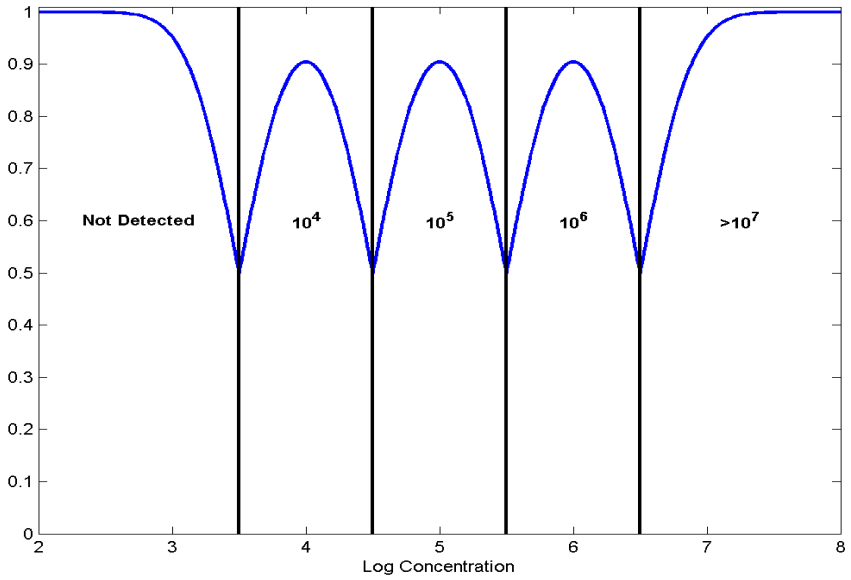

Figure 1. Model of Pneumonia Panel Bin Precision – probability of reporting same bin results for each replicate tested varies based on proximity to bin boundary.

Materials/methods: Precision testing was performed using multi-analyte samples containing bacteria at six concentrations (~10^2 - 10^7 copies/mL). Ninety replicates per sample were tested with Investigational Use Only pouches on multiple days, lots, and instruments. Precision was measured as the distribution (%) of replicates per bin at each input concentration and modeled to be as low as 50% for values at bin boundaries (Figure 1). Precision of relative reporting for multiple analytes in a sample at the same concentration was also evaluated.

Results: Consistent with the model, bin precision for high and low bins (Not Detected, ≥10^7 copies/mL) was 98-100%, precision for inputs at the bin center was ~90-100% and precision at bin

boundaries was as low as 57%. In samples with two analytes at the same concentration, bins were equal in >90% of replicates when inputs were near a bin center and in 50-75% of replicates at a bin boundary. Bin accuracy was reproducibly ±0.5-log of the input value.

Conclusions: The FilmArray Pneumonia Panel estimates bacterial abundance in lower respiratory specimens. Although lower precision for binned results (~50-90%) is unavoidable near bin boundaries, reliable assessment of relative abundance in polymicrobial samples is possible on a log scale, with precision-based considerations for interpretation of results within 1-log.

Note: FilmArray Pneumonia Panel has not been evaluated by the U.S. FDA or other regulatory agencies.